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EXAMINER	
CARTER, KENDRA D	

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1627	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/565,699	SCHELLER ET AL.	
	Examiner	Art Unit	
	KENDRA D. CARTER	1627	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 July 2011*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *9-83* is/are pending in the application.

5a) Of the above claim(s) *9,28 and 72-82* is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *10-27,29-71 and 83* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/GB/08) Paper No(s)/Mail Date *7/27/11*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The Examiner acknowledges the applicant's remarks and arguments of July 27, 2011 made to the office action filed February 14, 2011. Claims 9-83 are pending. Claims 9, 28 and 72-82 are withdrawn as belonging to a non-elected group. No claim amendments were submitted, thus claims 10-27, 29-71 and 83 were examined on the merits

For the reasons in the previous office action and below, the Applicant's arguments of all 35 U.S.C. 103(a) rejections were found not persuasive.

In light of no new claim amendments the previous 35 U.S.C. 103(a) rejections are below. The Applicant's arguments are addressed below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1) Claims 10-20, 27, 29-71 and 83 rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al. (US 4,501,890) in view of Corrigan et al. (Depression and Anxiety, 2000, vol. 1, pp. 58-65), Pfeiffer (Drugs Aging, 2002, vol. 19, no. 8, p. 561-570), in further view of Bronzava et al. (US 2005/0038015 A1), Marquis (US 6,350,773 B1), Rimpler et al. (US 2003/0180332 A1), and Dinan et al. (US 2005/0037983 A1).

Nichols et al. teach that the compounds of Formula III and IV are dopamine D2 agonist and are substantially devoid of other agonist or antagonist blocking activities. As D2 agonsits, the compounds are useful in treating Parkinson's syndrome and depression in mammals (see abstract and column 3, lines 20-26).

Nichols et al. does not teach that rotigotine treats any type of depression (claims 10, 12-15, 32-44 and 83) in humans (claim 11) or that rotigotine is administered parenterally, trandermally or mucosally (claim 17). Nichols et al. also does not teach the amounts or rotigotine to be administered (claims 18-20 and 45-59). Nichols et al. also

does not specifically teach the combination or non-combination with other pharmaceutical agents as in claims 16, 27, 29, 31, 60-71.

Corrigan et al. teach that pramipexole, a D2 receptor agonist, treated depression safely in individuals with major depression (see abstract).

Pfeiffer teaches that rotigotine is a known D2 receptor agonist and is a well tolerated candidate for transdermal Parkinson's Disease treatment (see page 566, column 2, 3.3 Rotigotine, first paragraph).

Bronzava et al. teach that D2 agonist can be combined with serotonine and/or noradrenaline reuptake inhibitory activity such as citalopram or fluxetine (see abstract and paragraph 19).

Marquis teaches a method and composition for the treatment of depression comprising the combination of a D2/D3 agonist and an antipsychotic such as thioridazine (i.e. an anxiolytic), fluphenazine, clozapine, haloperidol, thioridazine, risperidone and olanzapine (see column 1, lines 13-20; claims 3, 6 and 10). The combination can be in a unitary form or separately for simultaneous, separate or sequential administration (see paragraph 4, lines 1-8 and lines 55-63).

Rimpler et al. teach that rotigotine (N-0923) and its metabolites and prodrugs can be administered with other agents such as diphenhydramine (see paragraphs 89, 110 and 119).

Dinan et al. teach a method of treating depression with anti-inflammatory compounds such as ibuprofen (see claim 4) in combination with antidepressant compounds (see abstract). The combination can be in a unitary dosage form or in separate dosage forms intended for simultaneous or sequential administration to a subject in need of treatment (see page 6, paragraph 68).

To one of ordinary skill in the art at the time of the invention would have found it obvious and motivated to combine the method of Nichols et al. and the compound rotigotine to treat any type of depression (claims 10-15, 17, 30, 32-44 and 83) in humans because of the following teachings: 1) Nichols et al. provides the teaching that D2 agonist treat depression and Parkinson's disease; 2) Corrigan et al. teach that pramipexole, a D2 receptor agonist, treated depression safely in individuals with major depression (see abstract); and 3) Pfeiffer teaches that rotigotine is a known D2 agonist and well tolerated for transdermal Parkinson's disease in humans. Thus, since it is known that D2 agonist treat both depression and Parkinson's disease, one skilled in the art would be motivated to try a known effective D2 agonist that treats Parkinson's disease to also treat any type of depression.

In regards to the method being administered with or without another antidepressant (claims 16, 27, 29, and 31), Nichols et al. does not teach that the D2 agonist needed to be administered with another antidepressant to treat depression, thus it is understood that rotigotine would not have to be administered with another antidepressant. On the other hand, administering another anti-depressant would be obvious because both compounds would be used to treat depression. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

In regards to the amounts of administration in claims 18-20 and 45-59, it is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955.)

One skilled in the art would have found it obvious and motivated to administer rotigotine with the specific agents in claims 60-69 in a single or separate dose (claims 70 and 71) because Bornzava et al., Marquis, Rimpler et al. and Dinan et al. have demonstrated

the combination therapy of an anti-depressant with the claimed therapeutic agents that can be administered as a single dosage form or separately. "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). See also *In re Crockett*, 279 F.2d 274, 126 USPQ 186 (CCPA 1960); *Ex parte Quadranti*, 25 USPQ2d 1071 (Bd. Pat. App. & Inter. 1992); and *In re Geiger*, 815 F.2d 686, 2 USPQ2d 1276 (Fed. Cir. 1987).

2) Claims 23-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al. (US 4,501,890) in view of Corrigan et al. (Depression and Anxiety, 2000, vol. 1, pp. 58-65), Pfeiffer (Drugs Aging, 2002, vol. 19, no. 8, p. 561-570), in further view of Bronzava et al. (US 2005/0038015 A1), Marquis (US 6,350,773 B1), Rimpler et al. (US 2003/0180332 A1), and Dinan et al. (US 2005/0037983 A1) as applied to claims 10-20, 27, 29-71 and 83 above in further view of Lauterbach et al. (WO 02/089777 A1) and Hoffmann et al. (US 4,769028).

The teachings of Nichols et al., Corrigan et al., Pfeiffer, Bronzava et al., Rimpler, and Dinan et al. are as applied above.

Nichols et al., Pfeiffer, Corrigan et al., Bronzava et al., Rimpler, and Dinan et al. do not specifically teach rotigotine in the free base or hydrochloride salt (claim 23). The above references also do not teach rotigotine in a plaster with a matrix that gives constant plasma levels (claims 24-26).

Lauterbach et al teaches rotigotine in a silicone adhesive matrix transdermal system (see page 10, lines 1-5 and 23-27) that provide sufficient drug plasma levels to provide a satisfactory therapeutic effectiveness (i.e. constant plasma level; see page 6, lines 11-20). Ritogtine is in the form of its free base (see page 11, lines 12-15), in which the final product is a film (see page 14, line 6). Transdermal equivalents of the patch are comprised in the above system (see page 10, lines 23-30).

Lauterbach et al. does not teach a plaster.

Hoffmann et al. teach a medical plaster that releases the active agent in a matrix and comprises adhesive properties (see column 3, lines 47-61 and column 5, lines 1-32) such that the release rate of the active agent may be controlled.

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Nichols et al. and Pfeiffer and rotigotine free base (claim 23) in a plaster with a matrix that gives constant plasma levels (claims 24-26) because of the following teachings: 1) Lauterbach et al. teach a film of rotigotine in a

silicone adhesive matrix transdermal system (see page 10, lines 1-5 and 23-27) that provide sufficient drug plasma levels to provide a satisfactory therapeutic effectiveness (i.e. constant plasma level; see page 6, lines 11-20); and Hoffmann et al. provides teaching that adhesive medical plasters can be made to provide controlled release of active agents. Thus, one skilled in the art can make a plaster of the Lauterbach et al. transdermal system to provide controlled release of the rotigotine.

3) Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nichols et al. (US 4,501,890) in view of Corrigan et al. (Depression and Anxiety, 2000, vol. 1, pp. 58-65), Pfeiffer (Drugs Aging, 2002, vol. 19, no. 8, p. 561-570), in further view of Bronzava et al. (US 2005/0038015 A1), Marquis (US 6,350,773 B1), Rimpler et al. (US 2003/0180332 A1), and Dinan et al. (US 2005/0037983 A1) as applied to claims 10-20, 27, 29-71 and 83 above in further view of den Daas et al. (Naunyn-Schmiedeberg's Arch Pharmacol, 1990, 342, pp. 655-659).

The teachings of Nichols et al., Corrigan et al., Pfeiffer, Bronzava et al., Rimpler, and Dinan et al. are as applied above.

Nichols et al., Pfeiffer, Corrigan et al., Bronzava et al., Rimpler, and Dinan et al. do not specifically teach a prodrug of rotigotine as in claims 21 and 22.

Den Daas et al. teach that prodrugs of rotigotine (i.e. N-0437), including the acetyl, propionyl and the isobutyryl ester give activity after 2-3 hours after application and provides activity after 23 hours (see page 656, column 2, last paragraph), compared to the transdermal application of rotigotine. Possible reasons for the lag time difference for transdermal application between rotigotine and its prodrugs is that the limited amount of metabolizing enzymes in the skin first inactivate N-0437, and that subsequently the remaining free N-0437 can penetrate the circulatory system. The ester prodrugs are protected against metabolic attack in the skin and enter more rapidly (see page 658, column 2, paragraph 2).

To one of ordinary skill in the art at the time of the invention would have found it obvious to combine the method of Nichols et al. and Pfeiffer and a prodrug of rotigotine as in claims 21 and 22 because den Daas et al. teach that prodrugs of rotigotine are active before rotigotine transdermally because the ester prodrugs are protected against metabolic attack in the skin and enter more rapidly (see page 658, column 2, paragraph 2).

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive.

> The Applicant's continue to argue that there is no motivation to combine the seven cited documents because none of the documents teach that rotigotine is utilized in the treatment of depression. There is no reasonable expectation of success that rotigotine could effectively treat

depression. The evidence of record establishes the exact opposite conclusion. Effectiveness of a compound is not limited to its D2 receptor profile. Effectiveness is based, in part, by the compound's complete receptor profile as suggested by Scheller et al., Wang et al. and Bertaina-Anglade, which the Examiner fails to even address. In other words, if one of ordinary skill in the art could predict efficacy from D2 affinity, why would Wang and Bertaina-Anglade be unable to predict the effectiveness of apomorphine or ropinerole. Further, Wang concluded that the D2 agonist apomorphine (APO) has excessive stimulation of D1 receptor that may participate in the failure of coping behavior leading to learned helplessness and therefore in the pathophysiologic mechanisms underlying the development of depression. The opinion that one of ordinary skill in the art would not expect rotigotine to have an "excessive stimulation of the D1 receptor" by the Examiner is made without any citation to authority. Therefore, the evidence of record exemplifies that a D2 agonist and compound used in treating Parkinson's disease, like APO, can fail to treat depression, thus there is unpredictability in this art.

The Examiner disagrees because *at the time of the invention* rotigotine was known as a D2 agonist. Belluzzi et al.(see abstract), Beaulieu et al. (see abstract), Pfeiffer (see page 566, column 2, 3.3 Rotigotine, first paragraph), and even the applicant's (see specification, paragraph 5) all teach that rotigotine is a D2 agonist. Thus, *at the time of the invention* one skilled in the art would be motivated to use a D2 agonist to treat depression based on the teaching of Nichols et al., Pfeiffer, Bronzava et al, and Marquis. Further, Marquis teaches that a D2/D3 agonist can treat depression (see column 1, lines 13-20).

In regards to Wang et al., the reference indicates that "excessive" stimulation of D1 receptor may participate in the failure of coping behavior leading to learned helplessness and therefor in the pathophysiologic mechanisms underlying the

development of depression. To be clear, the Examiner reads Wang et al. to teach that at low doses of apomorphine (APO) the drug is effective in treating depression, and it is only at much higher doses was the drug ineffective (see page 67, left column last full paragraph). Thus, the "excessive" stimulation can be controlled by amount of drug administered. The Examiner would also like to demonstrate that APO has a 15:1 ratio selection of D2 over D1 (see Arnt et al., Psycopharmacology, 1985, vol 85, pp. 346-352; particularly page 348, results and Table 1 H-PIF versus H-SPI). Therefore, APO and rotigotine are similar in D2 activity since at the time of the invention, Belluzzi et al. teaches that rotigotine has a 15:1 ratio selection of D2 over D1 (see Belluzzi et al. abstract). Thus, it is not that rotigotine would be completely ineffective but at what concentrations the drug would be effective which is within the skill of the art through routine experimentation to determine. Therefore, it would be obvious to try rotigotine to treat depression with reasonable expectation of success for the reasons above.

In regards to Bertaina-Anglade, the reference teaches that rotigotine is effective in treating depression in low doses and possibly not at high doses (see abstract) which is in line with the teaching of Wang et al. The reference further supports the Examiner's arguments that it would be obvious to try rotigotine because of its mechanistic properties to treat depression despite some the fact that compounds with the same mechanistic pathway were either fully effective to treat depression as in the case of pramipexole or partially effective as in the case of ropinirole. Bertaina-Anglade still

found it obvious to try rotigotine to treat depression regardless of the results of ropinirole.

In response to applicant's argument that the examiner has combined an excessive number of references, reliance on a large number of references in a rejection does not, without more, weigh against the obviousness of the claimed invention. See *In re Gorman*, 933 F.2d 982, 18 USPQ2d 1885 (Fed. Cir. 1991).

> The Applicant further argues that rotigotine is structurally and chemically different than the compounds reported in Nichols, Corrigan and Muscat et al. The compounds of Nichols says that the compounds are substantially devoid of other agonist or antagonist activities other than acting as a D2 agonist. Further rotigotine demonstrates a preference for the D3 receptor not the D2 receptor. In regards to Corrigan, pramipexole is a non-ergolinic agonist of the D2 subfamily of dopamine receptors (D2, D3 and D4) having strongest affinity for D3. Thus, rotigotine clearly has a different chemical profile than pramipexole.

The Examiner continues to disagree because although the compounds of Nichols, Corrigan et al., Muscat and rotigotine are different, they are all D_2 agonist. Particularly, the compounds of Nichols and rotigotine both also treat Parkinson's disease through the D2 agonistic pathway. Thus, the method of treating depression and Parkinson's disease is effective through the D2 agonistic pathway. One skilled in the art would obviously try rotigotine for depression because of its mechanistic action and common therapeutic efficacy for Parkinson's disease as the Nichols compounds. Those, compounds of this type would obviously be combined together and with other

anti-depressant compounds in order to effectively treat depression and Parkinson's disease. Nichols does not need to provide a specific example of depression. It is within the skill of the art to test a compound that has the same mechanistic action to treat a condition, in which in this case is depression. In regards to pramipexole having the strongest affinity for D3, these results were not published until January 10, 2008 for the US application 11/764,907. Again, at the time of the invention, pramipexole was known for its activity to treat depression for its D2 activity as stated in the rejection above. This argument also holds true for rotigotine, Scheller et al. teach was published in 2009. At the time of the invention, rotigotine was known for its D2/D1 activities in which rotigotine has a higher affinity for D2. Nevertheless, the Examiner is not unilaterally saying that D2 is only mechanistic pathway to treat depression because Marquis teaches that depression can be treating with a D2/D3 agonist (see column 1, lines 13-20; claims 3, 6 and 10). The combination of reference provide enough evidence to try other compounds with this type mechanism for the same purpose of treatment.

> The Applicant further argues that there is no unreasonable amount of experimentation with no guidance from cited art. At best, the very large number of possible compounds provides only an invitation to try or experiment on the large number of agonists. Only with hindsight would one know that rotigotine has antidepressant properties. The same arguments hold true for the eight way rejection over Nichols, Pfeiffer, Bronzava, Marquis, Rimpler, Dinan, Lauterbach and Hoffman, and the seven way rejection over Nichols, Pfeiffer, Bronzava, Marquis, Rimpler, Dinan and den Daas.

The motivation to try rotigotine to treat depression over thousands of other compounds with just the same mechanistic pathway is its connection to the combined

effect of treating Parkinson's disease. Thus, one drug could be administered to treat Parkinson's disease and the depression experienced by these type of paients. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

> The Applicant incorporates its argument set forth in the February 10, 2010 response as the results of the 7 esters tested in den Daas indicated that at least 4 of the esters did not have activity; den Daas does not disclose, teach or suggest carbamate, carbonate, ketal, acetate, phosphate, phosphonate, sulfate or sulfonate prodrugs; and den Daas fails to cure the deficiencies of the other reference discussed above.

The Examiner maintains the reply to the arguments that were given in the February 10, 2010 response and are repeated below.

In response to den Das, the claims include that ester prodrugs can be used, in which den Das teach that prodrugs of rotigotine (i.e. N-0437), including the acetyl, propionyl and the isobutyryl ester give activity after 2-3 hours after application and provides activity after 23 hours (see page 656, column 2, last paragraph), compared to the transdermal application of rotigotine. Thus, one would be motivated to use the ester

prodrugs of rotigotine for the above reasons and further because the ester prodrugs are protected against metabolic attack in the skin and enter more rapidly (see page 658, column 2, paragraph 2). Den Das does not need to teach the other claimed prodrugs because the ester prodrugs are taught and thus teaching the limitations of claims

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KENDRA D. CARTER whose telephone number is (571)272-9034. The examiner can normally be reached on 9:00 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kendra D Carter

Examiner, Art Unit 1627

/SREENI PADMANABHAN/

Supervisory Patent Examiner, Art Unit 1627